UNITED STATES DISTRICT COURT

DISTRICT OF SOUTH DAKOTA

SOUTHERN DIVISION

KRISTEN LEE SLUIS, and GREG SLUIS, Plaintiffs, vs. ETHICON, INC., ETHICON, LLC, and JOHNSON & JOHNSON, Defendants.	4:20-CV-04165-RAL OPINION AND ORDER GRANTING PARTIAL SUMMARY JUDGMENT

This case began in the Southern District of West Virginia as part of the Ethicon multidistrict litigation (MDL). It is one of thousands of cases involving injuries patients allegedly suffered after being implanted with pelvic mesh products designed, manufactured, and sold by Ethicon, Inc., a wholly owned subsidiary of Johnson & Johnson. Plaintiffs Kristen and Greg Sluis sued Ethicon, Inc., Ethicon, LLC, and Johnson & Johnson (collectively "Ethicon"), claiming that two Ethicon products implanted in Mrs. Sluis were defectively designed and had inadequate warnings. Two motions filed in the MDL litigation remain pending and are now ripe for decision by this Court. This Court held a motion hearing on March 5, 2021. For the reasons explained below, this Court grants partial summary judgment to Ethicon.

I. Background[1]

[1]There are very few facts in the Sluises' short-form complaint, Ethicon's brief in support of their motion for summary judgment, and the Sluises' brief in opposition. Docs. 1, 68, 70. Although Ethicon's brief includes six statements of material fact, the Sluises did not provide a paragraph-by-paragraph response to these facts. Docs. 68, 70. Instead, they attached deposition testimony

In late September 2009, Dr. Kevin D. Benson implanted in Mrs. Sluis two Ethicon devices—the TVT to treat her stress urinary incontinence and the Prolift +M to treat her pelvic organ prolapse. Doc. 68 at 2 at ¶ 1; Doc. 29 at 4. According to the Sluises, the Prolift +M caused Mrs. Sluis serious injuries which have required multiple surgical mesh removal procedures. Doc. 70 at 1. In February 2012, the Judicial Panel on Multidistrict Litigation opened an MDL to coordinate pretrial proceedings of all Ethicon pelvic mesh-related litigation (Ethicon MDL). In re: Am. Med. Sys., Inc. Pelvic Repair Sys. Prods. Liab. Litig., 844 F. Supp. 2d 1359, 1360–62 (J.P.M.L. 2012); In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig., 299 F.R.D. 502, 508 (S.D.W. Va. 2014). The Ethicon MDL was assigned to the Honorable Joseph R. Goodwin in the Southern District of West Virginia. Am. Med. Sys., 844 F. Supp. 2d at 1362.

In August 2012, the Sluises filed this case in the Southern District of West Virginia as part of the Ethicon MDL. Doc. 1. Their short-form complaint pleaded the following claims: Negligence (Count I); strict-liability – manufacturing defect (Count II); strict liability – failure to warn (Count III); strict liability – defective product (Count IV); strict liability – design defect (Count V); common law fraud (Count VI); fraudulent concealment (Count VII); constructive fraud (Count VIII); negligent misrepresentation (Count IX); negligent infliction of emotional distress (Count X); breach of express warranty (Count XI); breach of implied warranty (Count XII); violation of consumer protection laws (Count XIII); gross negligence (Count XIV); unjust enrichment (Count XV); loss of consortium (Count XVI); punitive damages (Count XVII);

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and an expert report to their brief and argue that there are disputed questions of material fact. Docs. 70, 70-1, 70-2. The failure to comply with this Court's Local Rules concerning summary judgment motions and responses stems from the fact that at the time the parties were briefing the motion for partial summary judgment, this case was pending in the MDL district court. Because the testimony of surgeon Kevin Benson, M.D., is pivotal to the failure-to-warn claims, this Court directed that his entire transcript be filed and takes certain facts from his testimony. This Court also has gleaned facts from materials of record filed in the CM/ECF system.

discovery rule and tolling (Count XVIII). Doc. 1. Judge Goodwin assigned the cases in the Ethicon MDL to various "waves" to be prepared for trial. Doc. 28. The Sluises' case was assigned to Wave 10. Doc. 28.

There were two motions filed while this case was pending in West Virginia that remain pending today. First, Ethicon moved to exclude the case-specific opinions of Dr. Alan Garely, a urogynecologist. Doc. 66. Second, Ethicon moved for summary judgment on Counts I–IV and Counts VI–XV of the Sluises' complaint. Doc. 67. The Sluises opposed the motion as to Counts I, III, IV, and XIV, but did not oppose summary judgment on the other counts addressed in Ethicon's motion. Doc. 70.

In October 2020, Judge Goodwin transferred the Sluises' case to this Court. Doc. 79. This Court ordered the parties to stipulate to all the relevant pleadings from the Ethicon MDL and to advise how they wish to proceed with this case. Doc. 95. Ethicon responded that in addition to the motions just discussed, this Court must rule on its motions challenging the opinions of the Sluises' general experts. Doc. 114. In the Ethicon MDL, Judge Goodwin instructed the parties to file one Daubert[2] motion per challenged general expert and to file these motions in the main MDL rather than the individual member cases. Doc. 28 at 5–6. According to Ethicon, Judge Goodwin ruled on the parties' general Daubert motions in Wave 1 and then adopted these rulings in Waves 2–7 while also reserving arguments not addressed by the Wave 1 order for resolution by the trial court. Doc. 114 at 5. In Wave 10, Ethicon filed motions to exclude certain opinions of the general experts that many of the plaintiffs, including the Sluises, relied upon. Doc. 114 at 5. Judge Goodwin, however, did not enter orders on any Daubert motions in Wave 10. Doc. 114 at 5–6. This Court will permit the parties to file separate motions on each expert setting out the remaining

[2]Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993).

issues for disposition by this Court, but this Court intends to rule as Judge Goodwin has on issues not unique to this particular case. Very recently, the Sluises moved to strike the non-retained experts designated by Ethicon, arguing that they exceed the five-expert limit set by Judge Goodwin. Doc. 118.

II. Motion for Summary Judgement

A. Standard of Review

Under Rule 56(a) of the Federal Rules of Civil Procedure, summary judgment is proper "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Rule 56(a) places the burden initially on the moving party to establish the absence of a genuine issue of material fact and entitlement to judgment as a matter of law. Fed. R. Civ. P. 56(a); see also Celotex Corp. v. Catrett, 477 U.S. 317, 322–23 (1986). Once the moving party has met that burden, the nonmoving party must establish that a material fact is genuinely disputed either by "citing to particular parts of materials in the record" or by "showing that the materials cited do not establish the absence . . . of a genuine dispute." Fed. R. Civ. P. 56(c)(1)(A), (B); Gacek v. Owens & Minor Distrib., Inc., 666 F.3d 1142, 1145–46 (8th Cir. 2012); see also Mosley v. City of Northwoods, 415 F.3d 908, 910 (8th Cir. 2005) (stating that a nonmovant may not merely rely on allegations or denials). A party opposing a properly supported motion for summary judgment "may not merely point to unsupported self-serving allegations, but must substantiate his allegations with sufficient probative evidence that would permit a finding in his favor, without resort to speculation, conjecture, or fantasy." Reed v. City of St. Charles, 561 F.3d 788, 790–91 (8th Cir. 2009) (cleaned up and citations omitted). In ruling on a motion for summary judgment, the facts and inferences fairly drawn from those facts are "viewed in the light most favorable to the party opposing the motion." Matsushita Elec. Indus.

Co. v. Zenith Radio Corp., 475 U.S. 574, 587–88 (1986) (quoting United States v. Diebold, Inc., 369 U.S. 654, 655 (1962) (per curiam)).

B. Analysis

The Sluises do not contest summary judgment on Count II, Counts VI–XIII, and Count XV. Partial summary judgment for Ethicon will therefore enter on these claims. The Sluises also do not contest entry of summary judgment on claims related to the TVT, so partial summary judgment for Ethicon enters on any such claims. As to the other claims upon which Ethicon sought summary judgment, Ethicon argues that the Sluises' failure-to-warn claims fail because they can't show causation, that South Dakota does not recognize the Sluises' claim for "strict liability – defective product," and that the Sluises' negligence and gross negligence claims are duplicative of their strict liability claims. This Court addresses these arguments in turn.

1. Law on causation for failure-to-warn claims

The parties agree that South Dakota law applies because South Dakota is where Mrs. Sluis lives and underwent the surgery. Doc. 68 at 2–4; Doc. 70 at 2. South Dakota recognizes failure-to-warn claims under both negligence and strict liability, and the Sluises have pleaded claims under both theories. See Nationwide Mut. Ins. Co. v. Barton Solvents, Inc., 855 N.W.2d 145, 149–152 (S.D. 2014) (considering a failure-to-warn claim under both negligence and strict liability). Negligent failure-to-warn and strict liability failure-to-warn are distinct causes of action, but both torts require the plaintiff to prove that the failure to warn was the legal cause of their injuries. Karst v. Shur-Co., 878 N.W.2d 604, 613 (S.D. 2016); Nationwide Mut. Ins. Co., 855 N.W.2d at 150–51; Burley v. Kytec Innovative Sports Equip., Inc., 737 N.W.2d 397, 410–11 (S.D. 2007). "Legal cause means an immediate cause which, in the natural or probable sequence, produces the injury complained of. For legal cause to exist, the harm suffered must be a foreseeable

consequence of the act complained of." Berg v. Johnson & Johnson Consumer Cos., 983 F. Supp. 2d 1151, 1160 (D.S.D. 2013) (cleaned up and citation omitted). "[T]o prove causation in a failure-to-warn claim, a plaintiff must show that adequate warnings would have made a difference in the outcome, that is, that they would have been followed." Karst, 878 N.W.2d at 613 (cleaned up and citation omitted). "[T]he evidence must be such as to support a reasonable inference, rather than a guess, that the existence of an adequate warning may have prevented the accident before the issue of causation may be submitted to the jury." Id. at 614 (citation omitted).

Two doctrines are relevant to the parties' causation arguments. First, Ethicon relies on the learned intermediary doctrine. Under this doctrine, a manufacturer of medical devices or pharmaceuticals satisfies its duty to warn by providing the appropriate information to the treating physician. Ehlis v. Shire Richwood, Inc., 367 F.3d 1013, 1016 (8th Cir. 2004); Dan B. Dobbs et al., Dobbs' Law of Torts § 466 (2d ed. June 2020 update) (explaining that the learned intermediary doctrine applies "not only to drugs but also to medical devices and bodily implants that are usually accompanied by medical advice and supervision"). The treating physician then acts as a learned intermediary between the manufacturer and the patient, obviating the need for the manufacturer to warn the patient directly. Ehlis, 367 F.3d at 1016. In Schilf v. Eli Lilly & Co., this Court predicted that the Supreme Court of South Dakota would follow the learned intermediary doctrine. No. CIV 07-4015, 2010 WL 4024922, at *2 (D.S.D. Oct. 13, 2010), rev'd on other grounds, 687 F.3d 947 (8th Cir. 2012). The Eighth Circuit agreed with that prediction. Schilf, 687 F.3d at 949 (applying the learned intermediary doctrine); see also id. at 952 (Gruender, J., dissenting in part) (agreeing with the majority that South Dakota "likely would adopt the learned intermediary doctrine"). Although Schilf involved a drug manufacturer, this Court's reasons for predicting that the Supreme Court of South Dakota would follow the learned intermediary doctrine apply with equal force here.

Schilf, 2010 WL 4024922, at *2. Thus, this Court predicts that the Supreme Court of South Dakota would follow the learned intermediary doctrine in cases against a designer and manufacturer of medical devices.

Second, the Sluises argue that the "heeding presumption" applies under the Eighth Circuit's decision in Schilf. The heeding presumption comes from the last paragraph of comment j of § 402A of the Restatement (Second) of Torts. See Schilf, 687 F.3d at 949 (citing comment j when explaining the heeding presumption); 2 David G. Owen & Mary J. Davis, Owen & Davis on Products Liability § 11:20 (4th ed. May 2020 update) (stating that the heeding presumption "has its roots" in comment j).[3] The last paragraph of comment j reads: "Where warning is given, the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous." Restatement (Second) of Torts § 402A cmt j (Am. Law Inst. 1965). Comment j creates a presumption that an adequate warning will be read and heeded. Pavlik v. Lane Ltd./Tobacco Exps. Int'l, 135 F.3d 879, 883 (3d Cir. 1998); Garside v. Osco Drug, Inc., 976 F.2d 77, 81 (1st Cir. 1992). When warnings are present, this presumption favors the manufacturer because it "receives the benefit of the doubt" that the warning will be effective. Tuttle v. Lorillard Tobacco Co., 377 F.3d 917, 925 n.5 (8th Cir. 2004). However, courts have interpreted comment j as also giving the plaintiff a rebuttable presumption that, had an adequate warning been given, the plaintiff would have read and heeded it. Schilf, 687 F.3d at 949; Pavlik,135 F.3d at 883 (stating that it follows logically from comment j that "the law should also presume that, when no warning or an inadequate warning is provided, the end-user would have read and heeded an adequate

[3]Some jurisdictions base the heeding presumption on public policy rather than comment j. Benjamin J. Jones, Annotation, 38 A.L.R. 5th 683 § 2[a] (1996).

warning had one been given by the manufacturer"); Garside, 976 F.2d at 81. This presumption thus helps plaintiffs prove causation when there is no warning, or the warning is inadequate. Tuttle, 377 F.3d at 925 n.5.

The Eighth Circuit in Schilf predicted that South Dakota would "likely" adopt the heeding presumption. 687 F.3d at 949. It cited McElhaney v. Eli Lilly & Co., 739 F.2d 340 (8th Cir. 1984) (per curiam), to support this prediction but did not analyze the issue further. Schilf, 687 F.3d at 949. McElhaney was a short per curiam decision in which the Eighth Circuit upheld the district court's prediction that South Dakota would apply comments k and j of § 402A of the Restatement (Second) of Torts. 739 F.2d at 340–41. The Eighth Circuit in McElhaney noted that the Supreme Court of South Dakota had adopted § 402A to govern strict liability cases and had applied comment k. 739 F.3d at 340. The McElhaney decision concerned the paragraph of comment j stating that manufacturers must warn of certain types of dangers, and thus did not mention the heeding presumption. 739 F.3d at 340 n.1.

This Court addressed the heeding presumption portion of comment j in Lindholm v. BMW of North America, LLC, 202 F. Supp. 3d 1082 (D.S.D. 2016). Lindholm involved a strict liability claim against a car manufacturer for supplying an allegedly defectively designed jack. The plaintiffs' son had used the jack to lift his car to work beneath it when, tragically, the car fell off the jack and killed him. Id. at 1088. The son's use of the jack contravened the manufacturer's warnings that the jack should not be used to hold up the car while someone was underneath it. Id. at 1096. This Court predicted that the Supreme Court of South Dakota would apply comment j to a case like Lindholm given that court's frequent reliance on § 402A and specific citation to comment h, which cross references comment j. Id. The car manufacturer was thus entitled to "reasonably assume" that the warnings accompanying the jack would be read and heeded. Id.

(citation omitted). The Eighth Circuit agreed on appeal that the Supreme Court of South Dakota would apply comment j to the circumstances in Lindholm. Lindholm v. BMW of N. Am., LLC, 862 F.3d 648, 652 (8th Cir. 2017).

The Eighth Circuit's prediction in Schilf that South Dakota would apply the heeding presumption binds this Court absent an intervening decision by the Supreme Court of South Dakota indicating that the prediction in Schilf was wrong. See AIG Centennial Ins. Co. v. Fraley-Landers, 450 F.3d 761, 767–68 (8th Cir. 2006) ("Although our circuit has never specifically determined the binding effect of a state law determination by a prior panel, other circuits defer to prior panel decisions absent a subsequent state court decision or statutory amendment that makes the prior federal opinion clearly wrong. This provides us with an additional basis for our holding." (cleaned up and citations omitted)); Arena Holdings Charitable, LLC v. Harman Pro., Inc., 785 F.3d 292, 295–96 (8th Cir. 2015) (following a prior Eighth Circuit prediction about North Dakota law where subsequent North Dakota cases raised "some doubt" about the prediction but did "not stand as decisive legal authority" that the prediction was wrong); RehabCare Grp. E., Inc. v. Stratford Health Care Props., No. 14-0886-CV-W-FJG, 2015 WL 5098303, at *4 (W.D. Mo. Aug. 31, 2015) (noting that an Eighth Circuit decision about state law binds district courts "absent a subsequent state court decision or statutory amendment making" the decision incorrect); Brown v. La.-Pac. Corp., No. 4:12-cv-00102-SMR-HCA, 2014 WL 11513168, at *10 n.10 (S.D. Iowa Sept. 18, 2014) (explaining that "absent any clear instruction from the Iowa courts," the district court would need to defer to the Eighth Circuit's prior determination of Iowa law).

The are no such decisions from the Supreme Court of South Dakota, although its decision in Karst deserves mention. The plaintiff in Karst suffered brain damage when he was knocked to the ground while attempting to fix an electric tarp system on his grain trailer. 878 N.W.2d at 608.

He sued the manufacturer and seller of the tarp system for strict liability and negligence, alleging that the system did not come with adequate warnings. Id. at 607. The trial court granted the defendants' motion for summary judgment on the failure-to-warn claims, concluding that the plaintiff could not prove causation because he had not produced evidence that he read the warnings in the manual before the accident. Id. at 608. The plaintiff appealed, arguing that he was entitled to a presumption that he read the warnings. Id. at 615. Curiously, the plaintiff did not cite comment j or the heeding presumption to support this argument. Id. Instead, he relied on the presumption of due care afforded people injured or killed in moving-vehicle accidents. Id. For this presumption to apply, however, the injured person "must necessarily appreciate the danger inherent in the activity." Id. The Supreme Court of South Dakota declined to extend the presumption of due care to create a presumption that the plaintiff had read the warnings in the manual. Id. It reasoned that the presumption of due care was inconsistent with the plaintiff's concession of being unaware of the dangers associated with the electric tarp system and that testimony by the plaintiff's experts—opining that most people do not read the owner's manual for products they purchase—"negated" any basis for presuming that the plaintiff had read the manual for the tarp. Id.

Karst does not undermine Schilf to such a degree that this Court can refuse to apply the heeding presumption here. The Supreme Court of South Dakota did not mention comment j or the heeding presumption in Karst, let alone say that the presumption does not apply in South Dakota under any circumstances. Moreover, the circumstances in Schilf and this case are vastly different from those in Karst. Indeed, the plaintiff in Karst asked the Supreme Court of South Dakota to presume that he had read the instruction manual for his electric tarp system despite the plaintiff's own expert witnesses testifying that most people do not read the manual for products they purchase. 878 N.W.2d at 615. The Supreme Court of South Dakota's refusal to apply a

presumption to those facts, when the heeding presumption was never raised, says little about whether that court would apply the heeding presumption to cases like Schilf and this one, where a doctor is functioning as a learned intermediary between the defendant and the plaintiff. In short, Karst is not the sort of "decisive legal authority" courts have required before departing from prior federal predictions of state law. Arena Holdings, 785 F.3d at 295; see also AIG Centennial Ins. Co., 450 F.3d at 767–68 (explaining that other circuits defer to prior federal panel predictions about state law unless a later state court decision shows that the prediction was "clearly wrong" (quoting Broussard v. S. Pac. Transp. Co., 665 F.2d 1387, 1389 (5th Cir. 1982) (en banc))); FDIC v. Abraham, 137 F.3d 264, 269 (5th Cir. 1998) (explaining that a state court must issue "a contrary ruling squarely on point" before a prior federal panel's decision will be considered "clearly wrong"). Thus, this Court continues to predict, as has the Eighth Circuit twice, that South Dakota would apply the heeding presumption to a case like this. See Schilf, 687 F.3d at 949; Lindholm, 862 F.3d at 652.[4]

The Eighth Circuit decisions in Schilf and Lindholm do not predict how the heeding presumption would operate in South Dakota, and states differ over the effect the presumption has on the defendant's burden. Norwood v. Raytheon Co., 237 F.R.D. 581, 599 (W.D. Tex. 2006). Some states merely shift the burden of production to defendants, while other states shift both the burden of production and the burden of persuasion. Compare Kirkbride v. Terex USA, LLC, 798 F.3d 1343, 1351 (10th Cir. 2015) (stating that under Utah law, the heeding presumption requires

[4]There is likely a second issue about whether the Supreme Court of South Dakota would apply the heeding presumption to both strict liability failure-to-warn claims and negligent failure-to-warn claims. See Crowston v. Goodyear Tire & Rubber Co., 521 N.W.2d 401, 410 (N.D. 1994) (applying heeding presumption only to strict liability failure-to-warn claim and not to negligent failure-to-warn theory). Neither party briefed that issue and there is some question on whether enough evidence exists for the negligent failure-to-warn claims to survive summary judgment without the heeding presumption.

the defendant to rebut the presumption by a preponderance of the evidence), and Butz v. Werner, 438 N.W.2d 509, 517–18 (N.D. 1989) (explaining that the heeding presumption in North Dakota shifts the burden of proof to the defendant), with Pavlik, 135 F.3d at 883–84 (applying Pennsylvania law and stating that the plaintiff still retains the burden of persuasion under the heeding presumption and that the presumption "drops from the case" once the defendant meets its burden of producing evidence to rebut the presumption (citation omitted)), and Durkin v. Wabash Nat'l, No. 10-2013, 2013 WL 2352612, at *12 (D.N.J. May 29, 2013) (applying New Jersey law and explaining that if "the defendant satisfies its burden of production, that is, if defendant presents sufficient evidence to rebut the [heeding] presumption, . . . the presumption disappears and the plaintiff, consistent with his original burden of persuasion, must prove by a preponderance of the evidence that the failure to warn was a proximate cause of his injury").

Federal courts naturally look to state law to determine the effects of the heeding presumption. Fed. R. Evid. 302 ("In a civil case, state law governs the effect of a presumption regarding a claim or defense for which state law supplies the rule of decision."); Daniel v. Ben E. Keith Co., 97 F.3d 1329, 1332–33 (10th Cir. 1996) (looking to Oklahoma's evidence code and case law to determine the effect of the heeding presumption). South Dakota's rule on presumptions in civil cases says that a presumption shifts the burden of production but not the burden of persuasion:

> In all civil actions and proceedings, unless otherwise provided for by statute or by this chapter, a presumption imposes on the party against whom it is directed the burden of going forward with evidence to rebut or meet the presumption, but does not shift to such party the burden of proof in the sense of the risk of nonpersuasion, which remains throughout the trial upon the party on whom it was originally cast. When substantial, credible evidence has been introduced to rebut the presumption, it shall disappear from the action or proceeding, and the jury shall not be instructed thereon.

SDCL § 19-19-301; see also In re Estate of Pringle, 751 N.W.2d 277, 289–90 (S.D. 2008) (stating that a presumption does not shift the burden of proof). The "substantial, credible evidence" requirement in § 19-19-301 means that a presumption may be rebutted by "evidence that if uncontradicted would be sufficient to sustain a finding of the nonexistence of the presumed fact." In re Estate of Dimond, 759 N.W.2d 534, 538 (S.D. 2008). "[M]ere assertions, implausible contentions, and frivolous avowals will not avail to defeat a presumption." Id.

Based on SDCL § 19-19-301, this Court predicts that the heeding presumption in South Dakota shifts the burden of production to the defendant but not the burden of persuasion. Thus, once the plaintiff shows the lack of an adequate warning, a presumption arises that the plaintiff (or the learned intermediary) would have read and heeded the warning. The defendant then has the burden of producing "substantial, credible evidence" to rebut this presumption. SDCL § 19-19-301. The court decides whether the defendant has rebutted the presumption and, if the defendant has, the presumption disappears, and the jury receives no instruction on any such presumption. See id. ("When substantial, credible evidence has been introduced to rebut the presumption, it shall disappear from the action or proceeding, and the jury shall not be instructed thereon."); Bell v. E. River Elec. Power Coop, Inc., 535 N.W.2d 750, 754–55 (S.D. 1995) (concluding that substantial, credible evidence rebutted the presumption of due care, and that it was therefore not error for the trial court to refuse to instruct the jury on the presumption).

However, the mere rebuttal of the heeding presumption does not necessarily entitle the defendant to summary judgment. Instead, the defendant must show either that there is no genuine dispute of material fact on the adequacy of the warning or that an adequate warning would not have made a difference as a matter of law. See Pavlik, 135 F.3d at 884 ("While [defendant] need only produce evidence sufficient to support a finding contrary to the presumed fact to rebut the

presumption at trial, to satisfy Rule 56 the record must show that a reasonable fact finder would be bound to find [contrary to the presumed fact.]" (internal citation omitted)); see also Bachtel v. TASER Int'l, Inc., 747 F.3d 965, 971 (8th Cir. 2014) (explaining that a defendant is entitled to have causation determined as a matter of law if it produces "rebuttal evidence so strong that it would necessarily persuade any reasonable trier of fact that an adequate warning would have been futile" (cleaned up and citation omitted)).

2. There are questions of fact on causation

The Sluises allege that Ethicon failed to adequately warn of multiple risks stemming from implantation of the Prolift +M, including chronic inflammation, the product's propensity to degrade, and the product's inelasticity.[5] Doc. 2-1 at ¶¶ 41, 106. Ethicon does not move for summary judgment on the ground that it adequately warned Dr. Benson. Rather, it argues that the Sluises cannot show causation because Dr. Benson did not rely on warnings for the Prolift +M, knew the risks of implanting this product, and stands by his decision to use the Prolift +M on Mrs. Sluis. As this Court explains below, questions of fact preclude Ethicon's motion for summary judgment on the Sluises' failure-to-warn claims.

a. Dr. Benson's reliance on the warnings

Ethicon claims that the Sluises cannot show causation because Dr. Benson said that he did not rely on the Prolift +M's instructions for use (IFU). Ethicon points to the following testimony:

> **Defense Counsel:** Doctor, when you offered Mrs. Sluis the Prolift +M, is it fair to say that you did not rely on the IFU for Prolift +M?
> **Dr. Benson:** It's - - my recommendation for her is based on my clinical judgment.
> **Defense Counsel:** So what I said was true?
> **Dr. Benson:** Correct.

[5]The Sluises' expert on warnings is Dr. Susan Parisian, who is critical of the accuracy of Ethicon's Prolift +M product warnings. Doc. 83-1 at 22–118; Doc. 114-6 at 9–10.

Doc. 131 at 132–33.[6]

This testimony must be read in context, however. Defense counsel had asked Dr. Benson whether he relied on IFUs when offering alternative, non-mesh surgical procedures to Mrs. Sluis. Doc. 131 at 131–32. There are no IFUs for these procedures, so the answer, of course, was no. Doc. 131 at 131–32. Defense counsel then asked Dr. Benson whether he relied on the IFU when offering Mrs. Sluis the Prolift +M. Doc. 131 at 132. Consistent with his earlier answers about the non-mesh alternatives, Dr. Benson said that he relied on his clinical judgment rather than the IFU. Doc. 131 at 132. This testimony about reliance on clinical judgment does not foreclose a jury finding that adequate warnings in the Prolift +M would have changed Dr. Benson's conduct. After all, offering to implant a medical device in a patient's body involves far more than simply reading the instructions for using that product. The doctor must use training and expertise to evaluate the patient's needs and to weigh the risks and benefits of the procedure and device. It is therefore not surprising that Dr. Benson said he relied on his clinical judgment when offering Mrs. Sluis the Prolift +M.

Dr. Benson's testimony about relying on his clinical judgment does not mean that he didn't rely on the Prolift +M IFU to inform him of the product's risks. Indeed, Dr. Benson testified that he had looked at the Prolift +M IFU at some time before he implanted the product in Mrs. Sluis, Doc. 131 at 81, that information in an IFU is "a component of what we look to," Doc. 131 at 91, and that he would have done his "best" to follow any instructions in the IFU or other instructions from Ethicon concerning implantation of the Prolift +M, Doc. 131 at 111. Dr. Benson's deposition read in full reveals that he is a careful and well-qualified urogynecologist, aware of the extent to

[6]When citing to Dr. Benson's deposition transcript, this Court cites to the CMECF pagination rather than the transcript pagination.

which patients rely on him to know what is effective, what they can expect, and what the risks are. Doc. 131 at 147. Dr. Benson's medical records and testimony reveal that he discussed thoroughly with Mrs. Sluis what he knew at the time to be the risks of the surgery and use of the Prolift +M. Doc. 131 at 52–54, 57, 134–36, 144–47; Doc. 131-4.

There is a genuine issue of material fact on whether the IFU factored into Dr. Benson's use of the Prolift +M or his discussion with Mrs. Sluis about the product. See Fuller v. Ethicon Inc., 4:20-CV-00800-BRW, 2020 WL 4043517, at *2 (E.D. Ark. July 17, 2020) (finding a question of fact on whether the implanting surgeon had relied on a product's IFU where the surgeon said he merely glanced at the IFU in passing and did not rely on it when implanting the device but also acknowledged that had the defendants' sales representative informed him of a risk of which he was unaware, he would have included that risk in his informed consent discussion with his patients).

b. Dr. Benson's knowledge of the risks in recommending the Prolift +M

"Under the learned intermediary doctrine, the manufacturer's failure to provide the physician with adequate warnings of the risks associated with a particular prescription product is not the proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that the adequate warning should have communicated." Ehlis, 367 F.3d at 1016 (citation omitted); 2 Owen & Davis on Products Liability § 20:9 ("[W]hen the prescribing physician was aware of the possible side effects of a prescription drug or medical device, yet chose to use it regardless of the adequacy of the warning, then as a matter of law the adequacy of the warning was not the producing cause of the plaintiff's injury." (cleaned up and citation omitted)). Similarly, a plaintiff cannot prove causation when an adequate warning would not have changed the doctor's conduct. Schilf, 687 F.3d at 951.

Ethicon argues that Dr. Benson's deposition testimony establishes that he knew the risks associated with implanting the Prolift +M. Dr. Benson testified that in September 2009, he was aware of the following risks from surgery with the Prolift +M: acute and chronic vaginal or pelvic pain; vaginal scarring, infection, urinary problems, organ or nerve damage, bleeding, wound complications, inflammation, fistula formation, neuromuscular problems, one or more surgeries to treat an adverse event, recurrence or failure, foreign body response, erosion, exposure, or extrusion of any permanent sutures or the mesh, and contraction or shrinkage of tissues. Doc. 131 at 52–54.

The Sluises argue that Dr. Benson was not aware of the extent of certain risks associated with the Prolift +M and that the product's IFU downplayed these risks. The Sluises offered evidence from their expert Dr. Bernd Klosterhalfen that the mesh used in the Prolift +M elicits a chronic inflammatory response, Doc. 70-2 at 8–14, and is "inelastic which means it will stretch and remain elongated which results in pore collapse, folds and wrinkles," Doc. 70-2 at 26–27. Dr. Klosterhalfen also opined that the polypropylene in the Prolift +M is not inert and degrades in vivo over time. Doc. 70-2 at 36–42.

Dr. Benson testified that Ethicon never told him that their studies showed that the Prolift +M mesh elicits a chronic long-term inflammatory reaction and foreign body response, that the mesh did not remain soft and pliable upon implantation, or that the polypropylene in the Prolift +M actually degrades. Doc. 131 at 89–95. In fact, portions of the Prolift +M IFU discussed during Dr. Benson's deposition suggest that the IFU minimized these issues. Doc. 131 at 89–95; Doc. 131-9. Dr. Benson testified that if Ethicon had evidence of these issues—a chronic long-term inflammatory reaction and foreign body response, the mesh not remaining soft and pliable, and polypropylene degradation—he would have liked to have known of that evidence. Doc. 131 at 91–95. He also agreed that this evidence would have factored into his decision about whether to

use the Prolift +M as well as his discussion about the product with his patient. See Doc. 131 at 91 (saying that evidence of a chronic long-term inflammatory reaction and foreign body response "would be potentially a component" when discussing the risks of the Prolift +M with the patient); Doc. 131 at 93–94 (agreeing that he would have liked to have evidence that the mesh did not remain soft and pliable and that healing was impaired when considering the Prolift +M and discussing it with the patient); Doc. 131 at 94–95 (agreeing that evidence that the mesh used in the Prolift +M degraded would have factored into his decision about whether to use the product "[t]o some degree"); Doc. 131 at 95–96 (agreeing that if it were true that the mesh in the Prolift +M elicited a chronic inflammatory response, did not remain soft and pliable, and degraded, these issues would "play a role" when he spoke with his patient about the product and procedure options).

The Sluises have presented enough evidence to create a question of fact on whether Dr. Benson knew all the information about the Prolift +M the Sluises claim he should have received. Although Dr. Benson testified that he knew of certain risks associated with the Prolift +M, this testimony does not establish that he had "substantially the same knowledge as an adequate warning from the manufacturer should have communicated to him." Ehlis, 367 F.3d at 1016 (cleaned up and citation omitted); see also Heinrich v. Ethicon, Inc., 455 F. Supp. 3d 968, 975–76 (D. Nev. 2020) (finding question of fact on causation despite implanting doctor's testimony that he stood by his decision to recommend defendant's product where doctor did not know of certain issues with product, testified that these issues would have been part of the decision-making process in determining what products to offer his patients, and updated his consent procedure for mesh implant patients after receiving information from the FDA); Corley-Davis v. C.R. Bard, Inc., No. 2:16-cv-10811, 2018 WL 834945, at *2 (S.D.W. Va. Feb. 12, 2018) (denying motion for summary

judgment on the basis that the implanting physician knew of the relevant risks where the physician acknowledged "the absence of certain information from [Defendant's] warnings and confirm[ed] that such information would have been considered in forming her analysis of the product"); In re C.R. Bard, Inc., 2:10-cv-01224, 2013 WL 2431975, at *7–8 (S.D.W. Va. June 4, 2013) (finding question of fact on causation where implanting physician testified that he would have found information that he was not provided helpful in deciding whether he would have still implanted the device in the plaintiff).

Ethicon argues, however, that the Sluises still can't prove causation because Dr. Benson would have offered Mrs. Sluis the Prolift + M even if he had received an adequate warning. They point to the following testimony from Dr. Benson:

> **Defense counsel:** Doctor, in your medical judgment, were the benefits of the Prolift +M greater than the potential risks?
> **Dr. Benson:** Correct.
> **Defense counsel:** Doctor, in your medical judgment at that time, were the benefits of the TVT Retropubic greater than the potential risks?
> **Dr. Benson:** Correct.
> **Defense counsel:** Doctor, do you still stand by that recommendation today to use the Prolift + M and the TVT Retropubic?
> . . . .
> **Dr. Benson:** Well, I certainly still feel adamantly that in the right patient, in a patient with high risk, that it can be a reasonable option to provide.
> **Defense counsel:** And you still feel that way today; correct?
> **Dr. Benson:** I would, yes.

Doc. 131 at 72–73. This testimony occurred before the Sluises' attorney asked Dr. Benson about the Prolift +M eliciting a chronic long-term inflammatory reaction, the mesh not remaining soft and pliable upon implantation, and the polypropylene in the Prolift +M degrading.[7] Doc. 131 at

[7]Dr. Benson at times seemed skeptical of the claimed shortcomings in the Prolift +M when being questioned by the Sluises' counsel.

89–96. The Sluises' attorney later revisited Dr. Benson's testimony about recommending the Prolift +M:

> **Sluises' counsel:** You were asked earlier if you would do the same thing with Ms. Sluis insofar as use of the ProliftM [sic] today, if she presented to you. Do you recall that questioning?
> **Dr. Benson:** I think it certainly would be - - if it were available, it would be one of the things we'd offer.
> **Sluises' counsel:** She asked you whether - - if it was - - whether you would use it today under the same circumstances that you saw Ms. Sluis back in 2009. You recall that questioning, don't you?
> **Dr. Benson:** Yeah.
> **Sluises' counsel:** You can't use it today, though, can you?
> **Dr. Benson:** Correct.
> **Sluises' counsel:** Ethicon withdrew it from the market, didn't they?
> **Dr. Benson:** Correct.

Doc. 131 at 122. Nevertheless, towards the end of the deposition, Dr. Benson testified:

> **Defense counsel:** Do you agree that Prolift +M is a safe and effective product when used in the right patient?
> . . . .
> **Dr. Benson:** I agree.

Doc. 131 at 138.

Dr. Benson's testimony towards the end of his deposition is unclear whether he was speaking to his belief in 2009 or at the time of his deposition. There is enough ambiguity in Dr. Benson's testimony to leave a genuine issue of material fact on whether Dr. Benson would have recommended the Prolift +M even if he had been warned of the chronic long-term inflammatory reaction, the mesh not remaining soft and pliable upon implantation, and the polypropylene in the Prolift +M degrading.[8] Contrary to Ethicon's argument, Dr. Benson never said that he would have offered the Prolift +M to Mrs. Sluis even if he knew of these problems. Rather, Dr. Benson told defense counsel that he still believed that the Prolift +M was a reasonable option "in the right

[8]This Court of course is making no finding on whether such warnings were appropriate or required, but simply viewing the facts in the light most favorable to the Sluises as the nonmoving party.

patient;" he did not say that Mrs. Sluis was such a patient and was not asked whether he would still offer her the Prolift +M if he had substantially the same information as an allegedly adequate warning from Ethicon would have provided. Doc. 131 at 72. True, Dr. Benson's response to the Sluises' counsel was more specific in that he appeared to be saying that he would still offer the Prolift +M to Mrs. Sluis today if it were available. Doc. 131 at 122. But again, the question posed to Dr. Benson did not ask whether he would have recommended the Prolift +M to Mrs. Sluis if he knew about the actual risks of chronic long-term inflammation and the inelasticity and degradation of the mesh. Moreover, Dr. Benson testified that these risks, if true, would have factored into his decision about whether to use the Prolift +M and what to tell Mrs. Sluis. Doc. 131 at 91–96. Defendants' motion for summary judgment on the Sluises' claims that the Defendants failed to adequately warn them about the Prolift +M is denied.[9] See Bard, 2013 WL 2431975, at *7 (denying summary judgment where the doctor never explicitly said that he would not have used the device had he been provided additional warnings, but explained that the information would have been "helpful" and "nice to have").

[9]This Court recognizes that this case presents a close call on whether summary judgment on the failure-to-warn claims should enter. See Hanson v. Boston Sci. Corp., No. 2:13-cv-10653, 2016 WL 1448868, at *5 (S.D.W. Va. Apr. 12, 2016) (reasoning that mere evidence that the doctor's risk/benefit analysis "would have been impacted" was insufficient to withstand motion for summary judgment because it would require a reasonable juror "to speculate, based on mere *possibility*, that [the doctor] would have altered her decision to prescribe the product simply because she would have *considered* an additional factor in her risk/benefit calculus"); Twombly v. Boston Sci. Corp., No. 2:13-cv-23829, 2016 WL 1737118, at *6 (S.D.W. Va. May 2, 2016) (granting summary judgment on failure-to-warn claim because the record did "not include any evidence that [the treating doctor] would not have used or prescribed the products if the warnings were different"); Vanderwerf v. SmithKlineBeecham Corp., 529 F. Supp. 2d 1294, 1313–1314 (D. Kan. 2008) (granting summary judgment on failure-to-warn claim where the plaintiff presented evidence that the doctors would have passed on additional warnings had they been included but did not present evidence that these warnings would have prevented the injury). However, this Court, viewing the evidence in the light most favorable to the nonmoving party, finds that the Sluises narrowly have presented enough evidence when combined with the heeding presumption to avoid summary judgment on the failure-to-warn strict liability claim.

3. Strict liability – defective product

Count IV of the Sluises' complaint is entitled "Strict Liability – Defective Product." Doc. 1 at 4. Ethicon argues that there is no such cause of action in South Dakota. See Rynders v. E.I. Du Pont De Nemours & Co., 21 F.3d 835, 842 (8th Cir. 1994) (explaining that three classes of defects are actionable under South Dakota strict liability law: "manufacturing defects where individual products within a product line are improperly constructed, design defects involving the entire product line, and defect by failure to properly warn or instruct users of a product where such failure renders the product hazardous" (citation omitted)). The Sluises do not dispute this. Rather, they refer to the master complaint and argue that Counts IV and V should be read together as stating a strict liability – design defect claim under South Dakota law. Ethicon has not moved for summary judgment on Count V, which is entitled "Strict Liability – Design Defect." The Sluises argue, however, that if Count IV is dismissed, Ethicon might try to limit their strict liability – design defect claim during later proceedings. This Court denies Ethicon's motion for summary judgment on Count IV with the understanding that Counts IV and V state a single claim for strict liability – design defect. This Court will consider those two counts as merged into a single strict liability claim for an alleged design defect of the Prolift +M.

4. Duplicative claims

Ethicon asserts that the Sluises' "negligence-based claims are based on the same series of facts as their strict liability claims." Doc. 68 at 9. It argues that summary judgment is proper on the Sluises' negligence claims because these claims are "duplicative of and subsumed by" their strict liability claims. Doc. 68 at 9. In South Dakota, however, plaintiffs may plead more than one theory of liability in a products liability case. See Burley, 737 N.W.2d at 406–411 (analyzing

negligence and strict liability claims separately in a products liability case). Defendants' motion for summary judgment on Count I (negligence) is denied.

Count XIV of the Sluises' short-form complaint checks the box for a gross negligence cause of action. South Dakota law does not recognize a cause of action separate from a negligence claim for "gross negligence." See Estate of Stengle, 3:20-CV-03001-RAL, 2021 WL 858836, at *4 (D.S.D. Mar. 8, 2021). Thus, summary judgment on Count XIV will enter.

III. Motion to Exclude Certain Opinions of Dr. Garely

Ethicon argues that some of Dr. Garely's case-specific opinions must be excluded under Daubert. Daubert held that district courts serve as gatekeepers under Rule 702 of the Federal Rules of Evidence, admitting expert testimony only if it is both reliable and relevant. 509 U.S. at 589, 597; see also Kumho Tire Co. Ltd. v. Carmichael, 526 U.S. 137, 141 (1999) (extending the district court's gatekeeping function to all expert testimony). The current version of Rule 702 largely codifies Daubert and the cases applying it. Lauzon v. Senco Prods., Inc., 270 F.3d 681, 686 (8th Cir. 2001). The rule allows a qualified expert to testify if four criteria are met:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. The reliability of the expert's principles and methods can be judged by several factors, including (1) whether the scientific theory or technique can (and has been) tested; (2) whether the theory or technique has been published and undergone peer review; (3) whether the technique has a known or potential rate of error; (4) whether the theory or technique is generally accepted within the relevant scientific community; (5) whether the expertise was developed for

litigation or flowed from the expert's research; (6) whether the expert ruled out alternative explanations; and (7) whether the expert sufficiently connected his testimony to the facts of the case. Daubert, 509 U.S. at 593–94; Lauzon, 270 F.3d at 687. This is a non-exhaustive list, and courts may use or reject these factors as the case requires. Russell v. Whirlpool Corp., 702 F.3d 450, 456 (8th Cir. 2012).

A district court's inquiry under Rule 702 is "a flexible one," focusing on the "principles and methodology" the expert used rather than the correctness of the expert's conclusions. Daubert, 509 U.S. at 594–95. The rule favors admissibility, Johnson v. Mead Johnson & Co., LLC, 754 F.3d 557, 562 (8th Cir. 2014); Lauzon, 270 F.3d at 686, and courts should exclude an expert's opinion "only if it is so fundamentally unsupported that it can offer no assistance to the jury." Sappington v. Skyjack, Inc., 512 F.3d 440, 448 (8th Cir. 2008) (citation omitted). Still, courts will not admit opinion testimony "that is connected to existing data only by the *ipse dixit* of the expert." Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997); see also Marmo v. Tyson Fresh Meats, Inc., 457 F.3d 748, 758 (8th Cir. 2006) ("When the analytical gap between the data and the proffered opinion is too great, the opinion must be excluded."). The party offering the expert testimony must show its admissibility by a preponderance of the evidence. Lauzon, 270 F.3d at 686.

Dr. Garely is board certified in obstetrics, gynecology, and female pelvic medicine and reconstructive surgery. Doc. 66-1 at 3. He is a surgeon, professor, and scholar in the fields of obstetrics and gynecology and has regularly treated patients with mesh complications. Doc. 66-1 at 2–9.

The Sluises disclosed Dr. Garely as both a general causation and specific causation expert. Doc. 66-2 at 2. As to general opinions, the Sluises adopted Dr. Garely's report used by plaintiffs in earlier waves of the Ethicon MDL. Doc. 66-2 at 2. This general report addressed Ethicon's

Prolift kits.[10] Doc. 81-1 at 12. Among other things, Dr. Garely opined that the Prolift was defectively designed, Doc. 81-1 at 12–22, that the IFU for the Prolift did not provide adequate warnings, Doc. 81-1 at 25–33, and that Ethicon could have used a number of safer feasible alternative designs rather than the Prolift kits, Doc. 81-1 at 35. Judge Goodwin issued an order in Wave 1 ruling on some of Ethicon's challenges to Dr. Garely's general opinions while reserving ruling on others. Doc. 114-1. As relevant here, Judge Goodwin ruled that while Dr. Garely could testify "about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU," Dr. Garely did not have the necessary expertise to testify about what "information should or should not be included in an IFU." In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig., MDL No. 2327, 2016 WL 4582209, at *3 (S.D.W. Va. Sept. 1, 2016). Judge Goodwin reserved ruling on whether Dr. Garely's opinions about safer alternatives to Ethicon mesh products were reliable. Id. at *2–3.

Dr. Garely's case-specific report states that he used a process known as differential diagnosis to conclude that the Prolift +M caused Mrs. Sluis's postoperative complications, including subsequent surgeries, dyspareunia, chronic urinary tract infections, and urinary retention. Doc. 66-1 at 29–30, 34. Dr. Garely opined that the TVT[11] caused Mrs. Sluis's initial urinary retention but that her continued urinary retention after removal of the TVT device was caused by the Prolift + M:

> With respect to her urinary retention, the sling may have been too tight, which is a known and accepted complication from retropubic TVT slings, but the incidence of persistent retention following a sling revision is very low. The most reasonable explanation for the continued urinary retention is that the Prolift +M mesh caused

[10]Dr. Garely used the term "Prolift kits" to refer to the "Prolift Anterior, Prolift Posterior, and Prolift Total." Doc. 81-1 at 12.

[11]As stated above, the Sluises are no longer advancing claims based on the TVT and summary judgment on any such claims will enter.

> severe loss of bladder contractility resulting in the inability to generate enough pressure for the bladder to empty.

Doc. 66-1 at 34; see also Doc. 66-1 at 30 ("The TVT sling, acting to increase the closure pressure of the urethra clearly was responsible for the initial urinary retention, but without the placement of the Prolift +M mesh, that retention should have been reversible.").

Ethicon argues first that Dr. Garely's opinions regarding Mrs. Sluis's TVT are irrelevant because he does not say that the TVT caused her injuries. As the Sluises point out, however, Dr. Garely merely referenced the TVT to provide a factual background for his differential diagnosis and to explain why the TVT was not the cause of Mrs. Sluis's ongoing urinary retention. Ruling out potential causes of an injury is an important part of a differential diagnosis and Dr. Garely's discussion of the TVT in this context is not irrelevant. See Glastetter v. Novartis Pharms. Corp., 252 F.3d 986, 989 (8th Cir. 2001) (explaining that a differential diagnosis begins by ruling in all plausible causes of the plaintiff's injury and then ruling out the least plausible "until the most likely cause remains"); Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 202 (4th Cir. 2001) (noting that "a differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation" (citation omitted)). Moreover, Dr. Garely did not say that the TVT caused Mrs. Sluis's continued urinary retention and the Sluises don't argue that he did. Indeed, the Sluises are no longer bringing any claim concerning the TVT. Rather, Dr. Garely's opinion appears to be that the Prolift +M caused Mrs. Sluis's injuries, including her ongoing urinary retention. Doc. 69 at 3–4. Ethicon's motion to strike Dr. Garely's opinions about the TVT is denied.

Ethicon argues next that any opinions Dr. Garely has on product warnings must be struck because he does not connect any warning deficiency to Mrs. Sluis's injuries and is not qualified to testify about the adequacy of a product's warning. In the "Qualifications" section of his report,

Dr. Garely states that he has reviewed numerous IFUs for a "variety of medical products including mesh products," that he has "extensive clinical experience with IFUs" and in instructing patients about them, and that he has "gained expertise in IFUs" through this experience. Doc. 66-1 at 8. However, Dr. Garely does not offer any opinion about product warnings in his case-specific report. Doc. 66-1. Moreover, Judge Goodwin already concluded in Wave 1 that Dr. Garely did not have the expertise to testify about what an IFU should or should not include and the Sluises do not appear to challenge this ruling. This Court therefore denies Ethicon's motion to strike Dr. Garely's opinions on product warnings, but does so with the understanding that Dr. Garely will not be testifying about what information should or should not have been included in the Prolift +M's IFU.

Lastly, Ethicon seeks to exclude Dr. Garely's opinion in his case-specific report that "surgical and post-operative complications inherent to the Prolift +M are more likely to cause an adverse effect than alternative prolapse approaches such as native tissue repair and sacralcolpopexy, which were readily available at the time." Doc. 66-1 at 30. Ethicon argues that Dr. Garely fails to identify how an alternative procedure would have avoided Mrs. Sluis's injuries and that Judge Goodwin has rejected plaintiffs' attempts to substitute alternative surgical procedures for an alternative product design. The Sluises respond that Ethicon is trying to relitigate an issue that Judge Goodwin reserved for trial in his Wave 1 order on Dr. Garely's general report. They state that Dr. Garely will not be asked to give any "general expert opinion" on alternative procedures beyond those stated in his general report. Since the hearing, Ethicon filed a notice of supplemental authority on this issue, Doc. 132, and the Sluises filed a fifteen-page brief in response, Doc. 134. This Court denies Ethicon's motion to exclude Dr. Garely's opinion about alternative procedures, at least at this time. This Court may revisit the issue of what case-specific opinions the Sluises intend to elicit from Dr. Garely closer to the time of trial.

IV. Motion to Strike Non-Retained Experts

In every wave of the Ethicon MDL, Judge Goodwin entered a pretrial order limiting the parties to five expert witnesses each. Doc. 119-3 at 3. The pretrial order in Wave 10 read as follows:

> The parties may conduct general and specific expert discovery on all products at issue in this Wave. In light of the products involved in this Wave, the likelihood of overlap in expert opinion from one case to another (except as to specific causation) and the need to streamline discovery in these cases, **the plaintiffs and each defendant are limited to no more than five experts per case (exclusive of treating physicians).**

Doc. 28 at 4. Contrary to this pretrial order, Ethicon disclosed five retained experts, one "alternative retained expert,"[12] and ten "non-retained experts." Docs. 119-1, 119-2.

The Sluises now move to strike Ethicon's non-retained experts, arguing that they exceed the five-expert limit. Doc. 118. Both Judge Goodwin and district courts within the Eighth Circuit have rejected Ethicon's attempts to exceed the five-expert limit. See Wegmann v. Ethicon, Inc., 4:20-CV-00704 JAR, 2020 WL 5960923, at *6 (E.D. Mo. Oct. 8, 2020) (granting the plaintiff's motion to strike Ethicon's experts that exceeded the five-expert limit and explaining that Judge Goodwin "uniformly enforced" this limit); Kelly v. Ethicon, Inc., No. 20-CV-2036-CJW-MAR, 2020 WL 5949225, at *3–4 (N.D. Iowa Oct. 7, 2020) (striking Ethicon's experts that exceeded the five-expert limit). This Court grants the motion to the extent that Ethicon may have only five expert witnesses, but this does not preclude Ethicon from calling employees or former employees

[12]Ethicon's alternative retained expert is Timothy Ulatowski. Doc. 119-1 at 3. Ethicon claims that it would have used Ulatowski in place of one of their retained experts but for Judge Goodwin's ruling excluding FDA evidence, and say that they reserve the right to substitute Ulatowski in as a retained expert if that ruling is reversed. Doc. 119-1 at 3.

with scientific training and backgrounds to refute, for instance, negligence or punitive damage claims.

V. Conclusion

For the reasons stated above, it is hereby

ORDERED that Defendants' Motion for Partial Summary Judgment, Doc. 67, is granted in part and denied in part. The motion is granted as to Count II, Counts VI–XV, and any claims relating to the TVT, but is otherwise denied.

ORDERED that Plaintiffs' Motion to Strike Defendants' Non-Retained Experts, Doc. 118, is granted to the extent explained herein. It is further

ORDERED that Defendants' Motion to Exclude Certain Case-Specific Opinions of Dr. Garely, Doc. 66, is denied to the extent explained herein.

DATED this 26th day of March, 2021.

BY THE COURT:

/s/ Roberto A. Lange

ROBERTO A. LANGE
CHIEF JUDGE